

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO:
TRACK TWO SETTLEMENT

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

**TRACK TWO DEFENDANTS' SUPPLEMENTAL MEMORANDUM
IN SUPPORT OF TRACK TWO CLASS ACTION SETTLEMENT**

The Track Two Defendants submit this supplemental memorandum to address an issue raised by the Court at the August 8, 2011 hearing concerning the Track Two Settlement.

Specifically, the Court questioned why the Track Two settlement classes, unlike those in the Track One settlements, are not limited to purchasers who can prove that they paid "based upon AWP."¹ This memorandum explains why the broader classes in the Track Two Settlement are necessary, fair to members of the proposed classes, and should be approved.²

I. SETTLEMENT NEGOTIATIONS AND THE SETTLEMENT CLASSES

The Track Two Settlement was reached more than three years ago after seven months of hard-fought, arms-length negotiations that followed five years of intensive litigation. Among other difficulties in reaching agreement, the parties had to address claims with respect to 145 drugs, far more than were at issue in Track One. The diversity of the Track Two drugs and their therapeutic uses also presented challenges. Unlike the Track One drugs, which were predominantly brand name oncology drugs administered in a physician's office, the Track Two

¹ August 8, 2011 Hearing Transcript at 45-50.

² Class counsel has informed the Track Two Defendants that it supports leaving the classes as defined in the Track Two Settlement.

drugs were administered in a variety of inpatient and outpatient settings for a variety of different conditions and patient populations. Adding to the complexity, many of the Track Two drugs were multi-source products.

These complexities made it difficult if not impossible to establish that each payment for a Track Two drug was based on AWP. For example, the Court is familiar with the twin challenges of establishing (1) that a payment made under Medicare Part B for a multi-source drug using a common J-Code was for a particular defendant's drug, and (2) that the payment was affected by that defendant's AWP under Medicare's median-based reimbursement methodology.³ *In re Pharma. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 97 (D. Mass. 2007). Determining the basis of payment is further complicated in the hospital outpatient setting because, during substantial portions of the class period, Medicare's Hospital Outpatient Prospective Payment System ("OPPS") calculated beneficiary's copayment obligations using either a bundled reimbursement methodology, for which a drug's AWP was irrelevant, or based on cost derived from surveys of hospitals' acquisition costs and calculated as a discount from AWP.⁴ The complexities only worsen outside of the Medicare Part B context, where third-party payors establish a methodology for reimbursing for Track Two drugs (which in turn provides the basis for calculating coinsurance obligations) through private contracts with individual providers.⁵

³ The problem is compounded by the fact that over the course of the class period hundreds of the drugs that were reimbursed under the same J-Codes as defendants' products belonged to pharmaceutical companies that are not defendants in this case. See August 3, 2011 Declaration of Stephen J. Young in Support of the Track Two Class Action Settlement (Dkt 7696, Exh. B).

⁴ See June 15, 2006 Declaration of Steven J. Young in Support of Certain Defendants' Opposition to Class Certification ¶¶ 53-55 (Dkt. 2690).

⁵ *Id.* ¶¶ 92-94.

In light of these challenges, the parties could not be confident that a final judgment limited to those who paid “based on AWP” would achieve the complete finality that all parties sought as a core objective of the settlement. For this reason, the Track Two Settlement follows the model of the Lupron settlement in defining the class as purchasers of relevant drugs *without* requiring proof of payment based on AWP. *See In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 93 (D. Mass. 2005) (explaining that the settlement class included “‘all purchasers’ rather than purchasers who paid in reference to AWP”).

II. PRELIMINARY APPROVAL AND NOTICE TO THE CLASS

On July 2, 2008, the Court granted preliminary approval of the Track Two Settlement, which then, as now, defines the settlement classes without reference to payment “based on AWP.”⁶ The Court also ordered that notice be sent to class members directing them to submit Court-approved claims forms to participate in the settlement fund.⁷ The approved form of notice does not mention any requirement that claimants have purchased “based on AWP.”⁸ Nor do the claim forms require that claimants supply documentation or attest that they made purchases on the basis of AWP.⁹

The deadline for submission of claims forms has passed for each of the settlement classes. All told, thousands of claims were filed. Because the approved claims forms did not require it, the claims submitted to date do not include information sufficient to determine

⁶ July 2, 2008 Order Granting Preliminary Approval of the Track Two Settlements, Directing Notice to the Classes, and Scheduling Fairness Hearing at 2-3 (Dkt. 5426).

⁷ *Id.* at 7-8.

⁸ *See, e.g.*, Declaration of Eric Miller Regarding Mailing of Notice to Class Members, Exh. 1 (notice to third party payors with claim form) (Dkt. 5937); Class Plaintiffs’ Motion for Approval of Revised Notice Plan for Track 2 Settlement, Exh. 4 (notice to Class 1 consumers) & Exh. 5 (Class 1 consumer claim form) (Dkt. 7399).

⁹ *Id.*

whether claimants would be included in a narrower class that included only those who paid “based on AWP.”

III. ARGUMENT

The Track Two Settlement should be approved as written. The class definitions were carefully drawn with full knowledge of the problems that requiring proof of payment based on AWP would present. From the perspective of class members, proving membership in a class limited to those who paid based on AWP will often be difficult or impossible. Indeed, consumer class members have no way to determine and document that they paid a percentage of an amount set based on AWP. As litigation in this case demonstrates, even sophisticated experts disagree over whether certain payments were based on a particular defendant’s AWP, or based on AWP at all. The preliminarily approved class definition, by avoiding these problems, is consistent with the Manual for Complex Litigation’s admonition that class membership should be readily ascertainable. David F. Herr, *Annotated Manual for Complex Litigation*, Fourth 21.222 (2011) (collecting cases).

From the perspective of Track Two Defendants, limiting the settlement classes to those who paid based on AWP would undermine the finality and certainty for which they bargained in reaching the proposed settlement. In future lawsuits, the preclusive effect of a judgment based on the Court’s proposed class definitions would depend on whether the plaintiffs paid for the drugs at issue based on AWP. But, as explained above, answering that question can range from difficult and costly to impossible. The only certainty would be that collateral litigation would be encouraged in judicial forums far less knowledgeable about AWP than this Court.

The Court’s comments at the August 8 hearing may have reflected concern that the classes as defined in the Track Two Settlement could include persons or entities who have no

viable claims. However, as Judge Posner has explained, “a class will often include persons who have not been injured by the defendant’s conduct. ... Such a possibility or indeed inevitability does not preclude class certification.” *Kohen v. Pac. Inv. Mgmt. Co.*, 571 F.3d 672, 677 (7th Cir. 2009). This is particularly true in the context of a settlement class. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 620 (1997).

Indeed, Judge Stearns addressed this very issue in approving the Lupron settlement, which also defined the settlement class to include all purchasers of Lupron, not just those who purchased based on AWP. *See Lupron*, 228 F.R.D. at 78 n.3. Intervenors in that case argued that the settlement should not be approved because some Lupron purchasers might not have paid based on AWP. *Id.* at 89 n.29. Rejecting the argument, Judge Stearns explained that culling the few purchasers who did not pay based on AWP from the class would present “needle and haystack problems,” and the “the inclusion of all purchasers of Lupron in the class is an expeditious means of [e]nsuring that all purchasers who were affected by the scheme receive relief.” *Id.* The same considerations apply here and, for the same reasons, warrant approval of the settlement.

IV. CONCLUSION

For the foregoing reasons, Track Two Defendants respectfully request that the Court grant final approval to the Track Two Settlement.

Dated: August 26, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2011, I electronically filed the foregoing Track Two Defendants' Supplemental Memorandum in Support of Track Two Class Action Settlement using the CM/ECF system which will send notification of such filing(s) to all counsel of record.

/s Richard D. Raskin